

1 ROB L. PHILLIPS
2 FISHERBROYLES, LLP
3 5670 Wilshire Blvd., Suite 1800
4 Los Angeles, California 90036
5 Telephone: (702) 518-1239
6 rob.phillips@fisherbroyles.com
7 *Counsel for Plaintiff*

8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

DINESRX, LLC, an Indiana Limited
Liability Company;

Plaintiff,

v.

MEDISCA, INC., a company registered
to do business in the US, and DOES 1-
X,

Defendant.

Case No.:

COMPLAINT FOR:

- 1. BREACH OF CONTRACT; and**
- 2. BREACH OF IMPLIED COVENANT
OF GOOD FAITH AND FAIR DEALING**

COMPLAINT FOR DAMAGES

DINESRX, LLC (“DINESRX”), an Indiana Limited Liability Company (“Plaintiff”), files this Complaint for damages against MEDISCA, INC. (“MEDISCA”), a company registered to do business in the United States (“Defendant”) and alleges as follows:

PARTIES

1. DINESRX is an Indiana Limited Liability Company with a principal place of business at 312 Lacebark Street, Schererville, Indiana 46375.
2. MEDISCA is a Canadian company registered to conduct business in the United States with business offices at 661, Route 3, Unit C, Plattsburgh, New York 12901.

JURISDICTION AND VENUE

3. This is a civil action seeking damages for breach of contract and covenant of good

1 faith and fair dealing.

2 4. This action is brought pursuant to 28 U.S.C. §1332(a) (diversity) and Plaintiff seeks
3 damages in excess of \$75,000.

4 5. Venue is proper in this district pursuant to 28 U.S.C. §1391(c). Moreover, Section
5 19 of the subject agreement calls for exclusive jurisdiction in the County of New York, New York.

6 6. This Court has personal jurisdiction over MEDISCA as it has a place of business
7 in Plattsburgh, New York.

8 **BACKGROUND**

9 7. DINESRX is a leading consulting and advice firm in at least the areas of Sections
10 505(b)(2), 503(a) and 503(b) of the Federal Food, Drug, and Cosmetic Act (“FDCA”) and Section
11 340B of the Public Health Service Act (“PHSA”).

12 8. MEDISCA, according its website at www.medisca.com, has a mission to be the
13 global leader in providing quality compounding chemicals, products and turnkey solutions in the
14 compounding industry.

15 9. On or about June 29, 2017, DINESRX and MEDISCA entered into an Executive
16 Strategic Consultant Agreement (“Agreement”) under which DINESRX was to provide
17 MEDISCA information in formulating business strategy and achieving various business
18 development opportunities and projects such as DVCIPM, IP strategy and development,
19 establishing barriers to entry and business development, etc. (collectively deemed “Projects”). The
20 5 year term of the Agreement with one option to renew was required by MEDISCA and specifically
21 Mr. Tony DeSanto, MEDISCA’s President. A copy of the Agreement is attached as Exhibit 1.

22 10. One such Project (“The Project”) under the Agreement involved DINESRX
23 developing a strategic initiative to complete the clinical development of a compounded drug
24 product for use by Department of Defense personnel with an overarching goal of establishing
25 commercial reimbursement via the prescription benefit managers in the U.S. market.

26 11. On or about May 3rd, 2019, following the State of Ohio Governor’s Office
27 notifying MEDISCA and ZHF Consulting that funding for The Project would be eminent, the
28

1 MEDISCA workgroup for The Project was expanded to include Mr. Ajay Gupta, the VP Chief
2 Scientific Officer at MEDISCA. A series of teleconference calls related to The Project were
3 conducted from May 3rd, 2019 thru March 16th, 2020. Participants included Mr. AJ Gupta, Mr.
4 Philip Smyth, the Ohio State University research team including but not limited to Dr. Peter
5 Mohler, PhD, Vice Dean for Research of the OSU Wexner Medical Center, Andrew H. Glassman,
6 M.D., M.S. Chair of Orthopedics, James Borchers MD, Dr. Kunig, Jenny Carlson the OSU VP of
7 External Relations and Advocacy, the honorable former congressman Mr. Steve Austria of ZHF
8 Consulting, various ZHF Consulting personnel, the principal clinical investigators at OSU and
9 DINESRX.

10 12. Relative to The Project, on or about July 8, 2019, the State of Ohio notified
11 MEDISCA that the Governor had signed a state budget including Appropriation item 195664
12 allocating non-conventional funding in the form of a forgivable loan to Ohio State University for
13 \$5,200,000 as part of a Research Program to complete a clinical trial to demonstrate the efficacy
14 of a compounded drug product being sponsored by MEDISCA. It was anticipated that the clinical
15 development program should yield the first two clinical trials necessary to force commercial
16 reimbursement by prescription benefit managers in the U.S. market.

17 13. As set forth in paragraph 12, DINESRX participated in a number of teleconferences
18 with the above-named persons and notably was not privy to certain specific email and
19 teleconference communications occurring between May 3, 2019 and March 16, 2020 involving
20 Mr. AJ Gupta, Dr. Peter Mohler, Dr. Glassman and clinical principal investigators James Borchers
21 MD and Dr. Kunig. Following a series of confrontations between Mr. AJ Gupta and the research
22 team at Ohio State Wexner Medical Center, on or about October 2, 2019, Dr. Borchers voiced
23 concern about Mr. AJ Gupta's continued involvement in The Project.. MEDISCA's Mr. Philip
24 Smyth, Jenny Carlson, and to the best of Mr. Brett Dines' knowledge Dr. Borchers and Mr. Steve
25 Austria inquired about Mr. Brett Dines' ability to intervene. Mr. Brett Dines agreed and was able
26 to act as a buffer during teleconferences to ensure that the relationship between Mr. AJ Gupta and
27 the research team at Ohio State Wexner Medical Center did not jeopardize The Project.
28

14. On or about July 25, 2019, Mr. Philip Smyth, MEDISCA's Director of Federal Accounts and Strategic Initiatives, informed DINESRX that the Agreement was under review by Mr. Tony DeSanto, MEDISCA's President. The review was focused on the cost of the Agreement to MEDISCA. An email sent July 25th, 2019 to Mr. Philip Smyth from Mr. Tony DeSanto cited the cost of DINESRX's consulting agreement and requiring Mr. Philip Smyth to attend an August 5th, meeting of Medisca's executive team to discuss the same. Mr. Phillip Smyth informed DINESRX via a phone conference later that evening, "I want you to know our President is personally reviewing your consulting agreement due to costs. Medisca's Chief Scientific Officer whom is new to the project has recently been reviewing the project with our President. I wanted to know if you were planning on submitting the milestone for non-traditional funding?" Mr. Dines' responded, "Yes I am." Mr. Philip Smyth's response was, "Ok, Medisca will likely be holding a meeting on August 5th to review your executive consulting agreement and the cost implications."

15. On or about August 7th, 2019, Mr. Philip Smyth informed DINESRX that he was pleasantly surprised as to the results of his meeting with Mr. Tony DeSanto on or around August 5th, 2019. Mr. Philip Smyth conveyed to DINESRX he was relieved because no less than a week ago he was previously instructed by Mr. Tony DeSanto and MEDISCA's executive team to prepare to travel to the Ohio Statehouse in Columbus, Ohio and engage the Honorable State Senator Mr. Bob D. Hackett for the explicit purpose of scuttling the recently approved research program so as to remove the obligations to compensate the many vendors working on The Project and originating from the State of Ohio Budget appropriation item 195664.

16. Based on information and belief, on or about October 19, 2019, Mr. Philip Smyth and MEDISCA's Executive Team conducted a meeting to one again discuss The Project. Mr. Philip Smyth was informed that if he and MEDISCA's Chief Science Officer were unable to divert \$3,500,000 to \$3,800,000 of the \$5,200,000 non-conventional funding in the form of the forgivable loan earmarked for Ohio State University to MEDISCA, that the Research Program was to be scuttled. Based upon information and belief, the primary reason for potentially scuttling the Research Program involved the monies MEDISCA had obligated itself to pay various consultants

1 including DINESRX.

2 17. On or about December 20, 2019, Mr. Brett Dines participated in a teleconference
3 with three of MEDISCA's Directors, namely Vanessa Verni, Panagiota Danopoulos and Maurizio
4 De Stefano. The topics of discussion included the removal of AJ Gupta from The Project. Ms.
5 Verni instructed DINESRX that in order to make payments to DINESRX, MEDISCA would need
6 to institute a new set of preconditions that DINESRX would negotiate with Ohio State University
7 and be acceptable to MEDISCA. MEDISCA's terms and conditions required of Ohio State
8 University have yet to be defined in a Scope of Work Document, Memo of Understanding, Letter
9 of Intent, and or a Research Agreement for the purposes of allowing DINESRX to negotiate such
10 an agreement.

11 18. On or about January 9, 2020, DINESRX sent a demand letter to MEDISCA
12 detailing the monies it believed were owed to it under the Agreement and also requesting certain
13 information from MEDISCA which was necessary for DINESRX to complete its obligations under
14 the Agreement pursuant to the Research Program with Ohio State University. Copy of letter
15 attached as Exhibit 2. The requested information included (i) specific guidelines for the nature
16 and structure of a formal agreement with Ohio State University and (ii) tangible information
17 necessary to negotiate said agreement including: (a) clinical and product development strategy; (b)
18 lab notebooks related to clinical trial product development; (c) clinical trial material (drug product)
19 test results, clinical trial material protocols and interim test results, in addition to the raw data from
20 said test results; and (d) clinical trial material product research protocols for animal and human
21 testing previously proposed to Ohio State University and/or the state of Ohio. Counsel for
22 MEDISCA responded to the first demand letter on February 19, 2020. Copy of MEDISCA's first
23 response letter attached as Exhibit 3. MEDISCA's first responsive letter did not include the
24 requested information.

25 19. On March 5, 2020 DINESRX responded to MEDISCA's first responsive letter.
26 DINESRX's responsive letter attached at Exhibit 4. On or about March 31, 2020, counsel for
27 MEDSICA sent a letter purportedly terminating the Agreement and ending monthly payments
28

1 thereunder further damaging DINESRX. Termination Letter attached as Exhibit 5.

2 20. Up and through March 31, 2020 DINESRX had been working diligently to establish
3 the design space for a newly introduced drug product formulation as recently conceived in the
4 form of MEDISCA's response letter dated February 19, 2020.

5 21. DINESRX also had concerns related to at least one ingredient in the proposed drug
6 product as then and currently contained in Medisca's and LP3's library of compound formulations
7 that was to be used in the clinical trial at Ohio State University and being utilized in compounds
8 throughout the USA and promoted throughout the world. Specifically, one ingredient in the
9 formula and batch record production process as carried out by DoD Wright Patterson Air Force
10 Base was degrading into a neurotoxin. Upon being made aware of the formulation's ingredient to
11 degrade to the related species, DINESRX specifically designed out the subject ingredient from the
12 proposed drug product to be utilized in the clinical trial at Ohio State University. The degradation
13 of the ingredient into a neurotoxin obligated MEDISCA to notify customers of potential health
14 risks of utilizing the subject ingredient with the proposed drug product as contained within a
15 variety of published formulas, and the USP standard guidelines regarding shelf life of a product.
16 While DINESRX was not contracted to address regulatory risk, current USP Compendia
17 compliance and/or Current Good Manufacturing Practice (CGMP) compliance for MEDISCA,
18 DINESRX stands to be damaged by association should MEDISCA find itself liable for any harm
19 caused by the proposed drug product using the subject ingredient.

20 22. DINESRX also found it concerning that MEDISCA consistently failed to provide
21 DINESRX with timely DOD commission reports and payments as required under Schedule A of
22 the Agreement. Indeed, on several occasions, the DOD commission reports were not provided and
23 the commissions were not paid until after DINESRX contacted MEDISCA inquiring about the
24 same given the deadline for both had passed.

25 **COUNT I – BREACH OF CONTRACT**

26 23. Paragraphs 1 through 22 are incorporated herein by reference.

27 24. The Agreement has a natural expiration date of June 28, 2022. During the term of
28

the Agreement, DINESRX is to be compensated \$16,000 per month (as well as \$450 per hour for any services beyond 40 hours per month), an IRB Submission fee of \$100,000 and a tiered fee for securing non-traditional funding.

25. Even before purportedly terminating the Agreement, MEDISCA had improperly stopped making the \$16,000 monthly consulting payment to DINESRX.

26. MEDISCA's purported termination of the Agreement is effectively a breach of the Agreement as no cause exists for said termination and the Agreement does not provide for no cause termination. Moreover, MEDISCA breached the Agreement by ceasing the monthly consulting payments to DINESRX, and failing to provide the requested information including (i) specific guidelines for the nature and structure of a formal agreement with Ohio State University and (ii) tangible information necessary to negotiate said agreement including: (a) clinical and product development strategy; (b) lab notebooks related to clinical trial product development; (c) clinical trial material (drug product) test results, clinical trial material protocols and interim test results, in addition to the raw data from said test results; and (d) clinical trial material product research protocols for animal and human testing previously proposed to Ohio State University and/or the state of Ohio. Without the requested information, DINESRX was unable to complete its obligations under the Agreement.

27. As a direct and proximate result of MEDISCA's breach of the Agreement, DINESRX has been damaged in an amount no less than \$680,000 calculated as the sum of 36 months multiplied by the \$16,000 consulting fee per month (\$576,000) plus the IRB Submission fee of \$100,000 and the \$100,000 tiered fee for securing non-traditional funding in excess of \$500,000. The exact amount of damages to be determined at trial.

COUNT II – BREACH OF THE IMPLIED COVENANT OF

GOOD FAITH AND FAIR DEALING

28. Paragraphs 1 through 27 are incorporated herein by reference.

29. Every contract under New York law includes an implied covenant of good faith and fair dealing.

30. By seeking to undermine the Research Program with Ohio State University to avoid

1 the payment of consulting fees, MEDISCA has breached the implied covenant of good faith and
2 fair dealing associated with the Agreement.

3 31. As a direct and proximate result of Defendants' breaches of the implied covenant
4 of good faith and fair dealing, Plaintiffs are entitled to damages in an amount to be determined at
5 trial.

6 **PRAYER FOR RELIEF**

7 WHEREFORE, Plaintiff seeks the following relief:

- 8 A. a ruling that MEDISCA breached the Agreement;
- 9 B. a ruling that MEDISCA breached the implied covenant of good faith and fair
10 dealing associated with the Agreement;
- 11 C. an award of compensatory damages;
- 12 D. an award of attorneys' fees and costs; and
- 13 E. any additional relief the Court deems appropriate.

14
15 DATED this 10th day of September 2020.

16
17 Respectfully submitted,

18 **FISHERBROYLES, LLP**

19
20 /Rob L. Phillips/

21

ROB L. PHILLIPS, ESQ.
22 5670 Wilshire Blvd., Suite 1800
23 Los Angeles, CA 90036
24 Telephone: (702) 518-1239
25 *Counsel for Plaintiff*
26
27
28